

Multicentre Cancer Chemotherapy Group Randomised Trial of Adjuvant Chemotherapy for 'Early' Breast Cancer

Submission date 19/08/2002	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/08/2002	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 18/01/2016	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
B27

Study information

Scientific Title

Multicentre Cancer Chemotherapy Group Randomised Trial of Adjuvant Chemotherapy for 'Early' Breast Cancer

Study objectives

Not provided at time of registration

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Breast cancer

Interventions

Following initial local therapy, surgery with or without radiotherapy, patients are randomised to one of 2 treatment arms:

1. Arm A: Tamoxifen 10 mg twice daily for 12 months.
2. Arm B: A total of eight cycles of multidrug chemotherapy. Cyclophosphamide, vincristine and 5-fluorouracil to be given on day 1 and cyclophosphamide, vincristine and methotrexate on day 8 of each 3 week cycle.
3. Arm C: Multidrug chemotherapy with vincristine, methotrexate, chlorambucil and 5-fluorouracil repeated every 3 weeks for 8 cycles.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Tamoxifen, cyclophosphamide, vincristine, 5-fluorouracil, methotrexate, chlorambucil

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/2000

Completion date

31/12/2005

Eligibility**Key inclusion criteria**

1. Aged <70 years
2. Operable primary breast cancer with tumour <5 cm in greatest diameter
3. Histologically proven axillary node involvement
4. Adequate renal and liver function
5. No prior history of other malignant disease
6. No previous chemotherapy

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/2000

Date of final enrolment

31/12/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

MRC Clinical Trials Unit

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

Action Cancer Belfast (UK)

Sponsor details

1 Marlborough Park

Belfast

United Kingdom

BT9 6XS

+44 (0)289 080 3344

abc@email.com

Sponsor type

Research organisation

Website

<http://www.actioncancer.org>

ROR

<https://ror.org/02mf6dg38>

Funder(s)

Funder type

Research organisation

Funder Name

Action Cancer Belfast (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration